

Potential Adverse Cardiovascular Side Effects Following mRNA COVID-19 Vaccination

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Introduction

- COVID-19 pandemic
 - SARS-CoV-2 virus
 - Diagnosis via reverse transcriptase polymerase chain reaction (RT-PCR) test (Emery et al., 2004)
 - Myriad of symptoms experienced
 - Incubation period 2-14 days (Heymann, 2022)
 - Case fatality rate (CFR) of 2% (Chaudhary et al., 2021)
- Development of vaccine
 - Pfizer (BNT162b2), Moderna (mRNA-1273), Johnson & Johnson (JNJ-78436735)
 - Approved by the FDA for emergency use on December 11, 2020

Introduction (cont.)

- Epidemiology of COVID-19
 - 104,348,746 total cases in the U.S. with a weekly case rate of 30.6 per 100,000 (CDC, 2023)
 - 1,181,607 total deaths in the U.S. (CDC, 2024)
 - Incidence rates fluctuate throughout the year
- Epidemiology of the COVID-19 vaccine
 - As of March 4, 2024, 70% of the world's population has received at least one dose (Mathieu, 2024)
 - In the U.S., older adults present the highest percentage of fully vaccinated individuals (USAFacts, 2024)
 - Vaccination status varies among racial and ethnic groups

Methods

- Followed the research guidelines set forth during the completion of my senior honors thesis.
- Primarily utilized the Jerry Falwell Library, Google Scholar, and The National Library of Medicine.
- Search terms included:
 - “Cardiovascular effects of COVID vaccine in children/adults/older adults”
 - “Epidemiology of COVID” and “Epidemiology of COVID vaccine”

Results: Effects in Children

Characteristic	No. (%), by vaccine		
	Pfizer-BioNTech (n = 2,647)	Moderna (n = 612)	Total (N = 3,259)
Sex			
Female	1,296 (49.0)	300 (49.0)	1,596 (49.0)
Male	1,338 (50.6)	310 (50.7)	1,648 (50.6)
Unknown	13 (0.5)	2 (0.3)	15 (0.5)
Age range, yrs (median)	5–11 (8)	6–11 (8)	5–11 (8)
Ethnicity			
Hispanic or Latino	298 (11.3)	51 (8.3)	349 (10.7)
Non-Hispanic or Latino	2,293 (86.6)	549 (89.7)	2,842 (87.2)
Unknown	56 (2.1)	12 (2.0)	68 (2.1)
Race			
American Indian or Alaska Native	7 (0.3)	2 (0.3)	9 (0.3)
Asian	131 (5.0)	27 (4.4)	158 (4.9)
Black or African American	99 (3.7)	16 (2.6)	115 (3.5)
Native Hawaiian or other Pacific Islander	5 (0.2)	0 (—)	5 (0.2)
White	2,033 (76.8)	489 (79.9)	2,522 (77.4)
Multiracial	245 (9.3)	58 (9.5)	303 (9.3)
Other	71 (2.7)	8 (1.3)	79 (2.4)
Unknown	56 (2.1)	12 (2.0)	68 (2.1)
Total no. of COVID-19 vaccine doses received			
3	1,055 (39.9)	119 (19.4)	1,174 (36.0)
4	1,588 (60.0)	493 (80.6)	2,081 (63.9)
5	4 (0.1)	0 (—)	4 (0.1)
Vaccine co-administration^a			
Yes	565 (21.3)	105 (17.2)	670 (20.6)
No	2,082 (78.7)	507 (82.8)	2,589 (79.4)

Event†	No. (%) reporting reaction or health impact after vaccination ^a		
	Pfizer-BioNTech (n = 2,647)	Moderna (n = 612)	Total (N = 3,259)
Any injection site reaction	1,740 (65.7)	470 (76.8)	2,210 (67.8)
Pain	1,683 (63.6)	463 (75.7)	2,146 (65.9)
Swelling or hardness	229 (8.7)	64 (10.5)	293 (9.0)
Redness	211 (8.0)	64 (10.5)	275 (8.4)
Itching	123 (4.7)	21 (3.4)	144 (4.4)
Any systemic reaction	1,215 (45.9)	379 (61.9)	1,594 (48.9)
Fatigue	798 (30.2)	278 (45.4)	1,076 (33.0)
Headache	534 (20.2)	211 (34.5)	745 (22.9)
Fever	512 (19.3)	198 (32.4)	710 (21.8)
Myalgia	353 (13.3)	145 (23.7)	498 (15.3)
Chills	247 (9.3)	103 (16.8)	350 (10.7)
Nausea	208 (7.9)	89 (14.5)	297 (9.1)
Abdominal pain	182 (6.9)	56 (9.2)	238 (7.3)
Vomiting	115 (4.3)	39 (6.4)	154 (4.7)
Joint pain	106 (4.0)	41 (6.7)	147 (4.5)
Diarrhea	74 (2.8)	15 (2.5)	89 (2.7)
Rash	37 (1.4)	8 (1.3)	45 (1.4)
Any health impact	506 (19.1)	196 (32.0)	702 (21.5)
Unable to attend school	355 (13.4)	114 (18.6)	469 (14.4)
Unable to perform normal daily activities	298 (11.3)	149 (24.4)	447 (13.7)
Needed medical care	49 (1.9)	13 (2.1)	start highlight62 (1.9)end highlight
Outpatient clinic	30 (1.1)	7 (1.1)	37 (1.1)
Telehealth	10 (0.4)	4 (0.7)	14 (0.4)
Other	12 (0.5)	3 (0.5)	15 (0.5)
Emergency department visit	4 (0.1)	0 (—)	4 (0.1)
Hospitalization	0 (—)	0 (—)	0 (—)

Hause, A. M., Marquez, P., Zhang, B., Su, J. R., Myers, T. R., Gee, J., Panchanathan, S. S., Thompson, D., Shimabukuro, T. T., & Shay, D. K. (2023). Safety monitoring of bivalent COVID-19 mRNA vaccine booster doses among children aged 5–11 years — United States, October 12–January 1, 2023. *MMWR. Morbidity and Mortality Weekly Report*. 72(2), 39–43. <https://doi.org/10.15585/mmwr.mm7202a5>

Results: Effects in Adolescents

Table 2. Presentation with myopericarditis, subclinical myocarditis, and pericarditis after second dose vaccination.

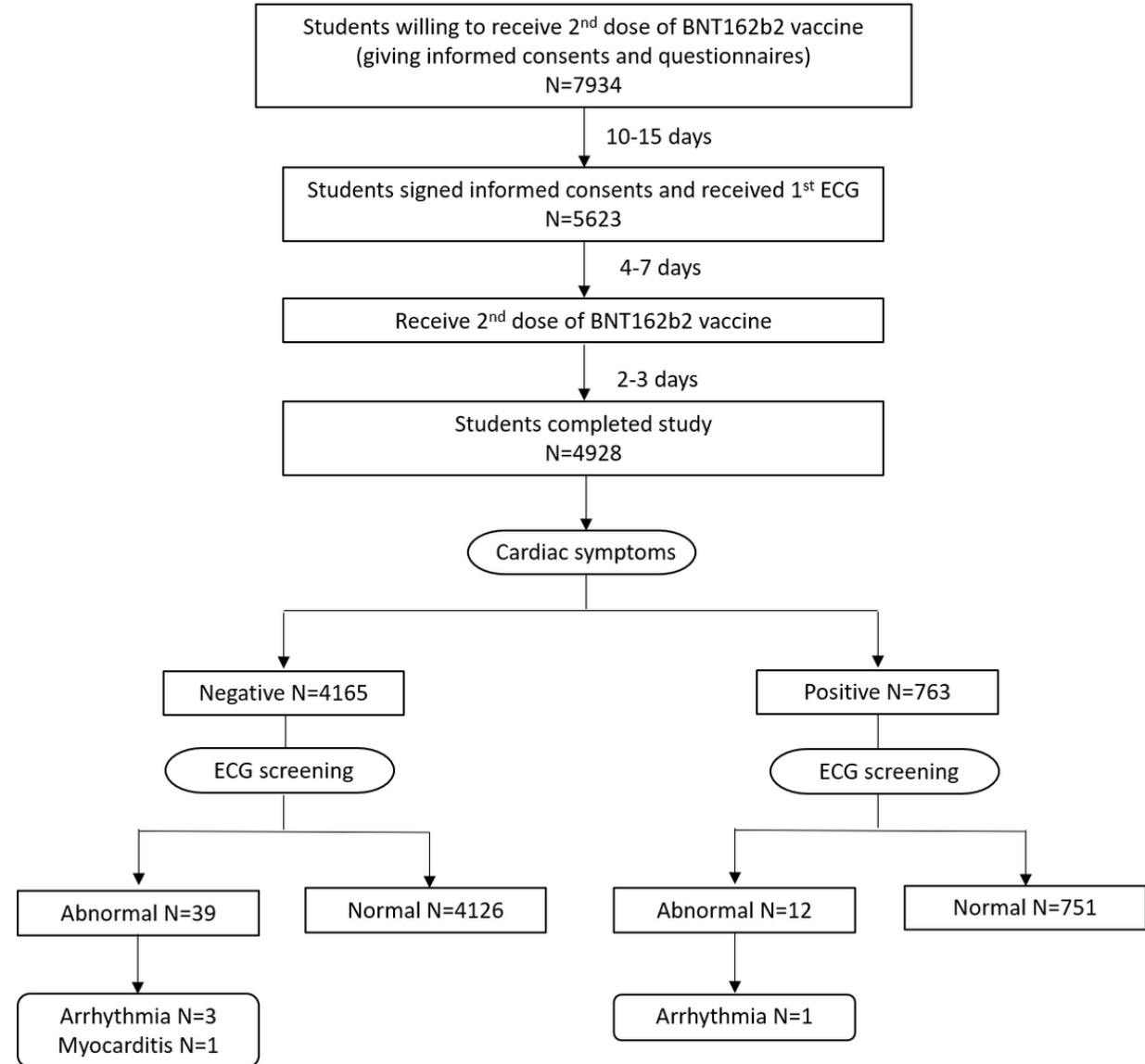
Variable	Value
Presenting symptoms and signs—Number/total number (%)	
Chest pain	3/7 (42.86)
Chest discomfort	3/7 (42.86)
Pericardial effusion	3/7 (42.86)
Fever	4/7 (57.14)
Headache	2/7 (28.57)
Palpitation	1/7 (14.29)
Dyspnea	1/7 (14.29)
Vital signs on day of symptoms (Mean ± SD)	
Temperature—°C	36.4 ± 0.4
Blood pressure—mmHg	
Systolic	114.9 ± 10.9
Diastolic	70.7 ± 7.8
Heart rate—beats/min	92.71 ± 21.3
Shock-Number/total number. (%)	0/7 (0)
Electrocardiographic findings—Number/total number (%)	
Normal sinus rhythm	1/7 (14.29)
Sinus rhythm with sinus arrhythmia	2/7 (28.57)
Diffuse ST elevation with PR depression	1/7 (14.29)
Sinus arrhythmia with PAC	1/7 (14.29)
Sinus tachycardia	1/7 (14.29)
Junctional escape rhythm	1/7 (14.29)

Table 4. Electrocardiographic findings after second vaccine dose.

Rhythm	Number (n = 301)
Normal sinus rhythm	247 (82.06%)
Sinus rhythm with sinus arrhythmia	22 (7.31%)
Sinus tachycardia	20 (6.64%)
Sinus bradycardia	4 (1.33%)
Premature atrial contraction (PAC)	3 (1%)
Premature ventricular contraction (PVC)	2 (0.66%)
Junctional escape rhythm	1 (0.33%)
Ectopic atrial rhythm	1 (0.33%)
Diffuse ST elevation with PR depression	1 (0.33%)

Data are reported as percentage (%). PAC, premature atrial contraction; PVC, premature ventricular contraction.

Results: Effects in Young Adults



Results: Effects in Adults

Trial	Total events (events per 10,000 participants) ^a		Risk difference per 10,000 participants (95 % CI) ^e	Risk ratio (95 % CI) ^e
	Vaccine	Placebo		
Serious adverse events				
Pfizer	127 (67.5)	93 (49.5)	18.0 (1.2 to 34.9)	1.36 (1.02 to 1.83)
Moderna	206 (135.7)	195 (128.6)	7.1 (-23.2 to 37.4)	1.06 (0.84 to 1.33)
Combined	333 (98.0)	288 (84.8)	13.2 (-3.2 to 29.6)	1.16 (0.97 to 1.39)
Serious adverse events of special interest				
Pfizer	52 (27.7)	33 (17.6)	10.1 (-0.4 to 20.6)	1.57 (0.98 to 2.54)
Moderna	87 (57.3)	64 (42.2)	15.1 (-3.6 to 33.8)	1.36 (0.93 to 1.99)
Combined	139 (40.9)	97 (28.6)	12.5 (2.1 to 22.9)	1.43 (1.07 to 1.92)

Results: Effects in Older Adults

Patient Characteristic	General 65 + FFS ^b	mRNA-1273 ^c	BNT162b2	Ad26 COV2.S	SMD - Comparison with General FFS ^c		
					mRNA-1273	BNT162b2	Ad26 COV2.S
Total	25,390,578	15,761,718	15,896,042	576,698			
Nursing Home Residency Status							
Nursing Home Resident	578,908 (2.3)	324,991 (2.06)	711,437 (4.48)	12,948 (2.25)	0.02	0.12	0.00
Non-Nursing Home Resident	24,811,670 (97.7)	15,436,727 (97.94)	15,184,605 (95.52)	563,750 (97.75)	0.02	0.12	0.00
Age (years)							
65-74	13,661,915 (53.8)	8,333,648 (52.87)	8,080,719 (50.83)	347,687 (60.29)	0.02	0.06	0.13
75-84	8,288,448 (32.6)	5,369,646 (34.07)	5,383,100 (33.86)	166,011 (28.79)	0.03	0.03	0.08
85+	3,440,215 (13.5)	2,058,424 (13.06)	2,432,223 (15.30)	63,000 (10.92)	0.01	0.05	0.08
Sex							
Female	14,191,641 (55.9)	9,010,306 (57.17)	9,324,988 (58.66)	319,812 (55.46)	0.03	0.06	0.01
Male	11,198,935 (44.1)	6,751,412 (42.83)	6,571,054 (41.34)	256,886 (44.54)	0.03	0.06	0.01
Race/Ethnicity							
Asian	529,362 (2.1)	320,757 (2.04)	341,530 (2.15)	10,113 (1.75)	0.00	0.00	0.03
Black	1,728,808 (6.8)	764,033 (4.85)	898,467 (5.65)	33,219 (5.76)	0.08	0.05	0.04
Hispanic	398,426 (1.6)	146,371 (0.93)	162,556 (1.02)	6,578 (1.14)	0.06	0.05	0.04
Alaskan Native/Native American	117,539 (0.5)	64,557 (0.41)	67,878 (0.43)	1,421 (0.25)	0.01	0.01	0.04
White	21,584,886 (85.0)	13,776,628 (87.41)	13,714,047 (86.27)	504,406 (87.46)	0.07	0.04	0.07
Other	448,630 (1.8)	282,212 (1.79)	299,951 (1.89)	7,555 (1.31)	0.00	0.01	0.04
Missing/Unknown	582,927 (2.3)	407,160 (2.58)	411,613 (2.59)	13,406 (2.32)	0.02	0.02	0.00
Urban/Rural							
Urban	19,415,683 (76.5)	11,855,600 (75.22)	1,346,1164 (84.68)	436,146 (75.63)	0.03	0.21	0.02
Rural	5,811,513 (22.9)	3,822,143 (24.25)	2,359,912 (14.85)	138,341 (23.99)	0.03	0.21	0.03
Missing/Unknown	163,382 (0.6)	83,975 (0.53)	74,966 (0.47)	2,211 (0.38)	0.01	0.02	0.03

Outcomes, by Vaccine Brand	Vaccine Brand	Observed Person Time (Days)	Number of Doses	Number of Observed Outcomes (as of 01/15/2022) ^a	Relative Risk of Observed vs Expected (Any Dose; 01/15/2022) ^b	Signal Identified ^c
Acute Myocardial Infarction	BNT162b2	402,380,589	15,747,074	13,293	0.97	Yes - 2/27/2021 (RR = 1.42)
	mRNA-1273	423,244,936	15,628,229	12,909	0.94	No
	Ad26 COV2.S	13,156,815	570,434	548	1.30	No
Deep Vein Thrombosis	BNT162b2	402,057,021	15,600,926	12,871	0.88	No
	mRNA-1273	424,775,904	15,507,286	11,342	0.78	No
Pulmonary Embolism	Ad26 COV2.S	13,126,819	567,190	480	1.07	No
	BNT162b2	404,173,653	15,684,098	9,443	1.15	Yes - 2/27/2021 (RR = 1.54)
Disseminated Intravascular Coagulation	mRNA-1273	426,520,976	15,571,477	8,996	1.08	No
	Ad26 COV2.S	13,184,317	569,676	346	1.34	No
	BNT162b2	405,993,894	15,891,008	355	0.92	Yes - 3/13/2021 (RR = 1.91)
Non-hemorrhagic Stroke	mRNA-1273	426,696,226	15,757,044	303	0.80	No
	Ad26 COV2.S	13,297,825	576,495	14	1.11	No
	BNT162b2	403,683,932	15,799,026	7,882	0.85	No
Hemorrhagic Stroke	mRNA-1273	424,648,679	15,680,668	7,646	0.83	No
	Ad26 COV2.S	13,214,072	572,972	297	1.06	No
	BNT162b2	405,580,548	15,874,528	2,128	0.96	No
Immune Thrombocytopenia	mRNA-1273	426,350,816	15,744,161	1,958	0.88	No
	Ad26 COV2.S	13,283,534	575,871	77	1.12	No
	BNT162b2	554,443,925	15,857,949	1,670	1.26	Yes - 4/24/2021 (RR = 1.44)
Myocarditis/Pericarditis	mRNA-1273	573,697,153	15,725,918	1,526	1.14	No
	Ad26 COV2.S	19,848,219	575,565	62	1.34	No
	BNT162b2	555,100,577	15,876,623	1,415	1.10	No
Guillain-Barre Syndrome	mRNA-1273	574,346,394	15,743,573	1,259	0.97	No
	Ad26 COV2.S	19,865,485	576,075	48	1.04	No
	BNT162b2	532,555,069	15,892,318	69	1.14	No
Bell's Palsy	mRNA-1273	536,703,703	15,758,009	53	0.86	No
	Ad26 COV2.S	19,582,979	576,548	**	3.85	No
	BNT162b2	575,124,693	16,453,363	3,618	1.12	No
Encephalomyelitis/Encephalitis	mRNA-1273	594,439,852	16,299,826	3,505	1.07	No
	Ad26 COV2.S	20,810,662	603,113	133	1.13	No
	BNT162b2	561,415,207	16,479,530	153	1.21	No
Transverse Myelitis	mRNA-1273	572,296,487	16,324,225	120	0.98	No
	Ad26 COV2.S	20,648,928	604,024	**	1.68	No
	BNT162b2	541,656,398	15,892,229	66	1.36	No
Narcolepsy	mRNA-1273	552,699,497	15,757,865	48	1.00	No
	Ad26 COV2.S	19,700,796	576,539	**	1.10	No
	BNT162b2	555,189,780	15,879,173	623	1.15	No
Appendicitis	mRNA-1273	574,433,145	15,745,902	537	0.98	No
	Ad26 COV2.S	19,864,965	576,089	23	1.15	No
	BNT162b2	548,982,786	15,880,177	1,180	1.06	No
Appendicitis	mRNA-1273	564,851,514	15,745,889	1,190	1.04	No
	Ad26 COV2.S	19,785,242	576,111	37	0.86	No

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Results: Effects by Gender

	DP1		DP2		DP3		DP4	
	n	%	n	%	n	%	n	%
Total myocarditis or pericarditis events	154	100%	64	100%	94	100%	99	100%
Age (years)								
18-25	64	42%	21	33%	34	36%	34	34%
26-35	15	10%	10	16%	16	17%	21	21%
36-45	24	16%	11	17%	14	15%	14	14%
46-55	26	17%	9	14%	13	14%	14	14%
56-64	25	16%	13	20%	17	18%	16	16%
Sex								
Female	43	28%	27	42%	25	27%	32	32%
Male	111	72%	37	58%	69	73%	67	68%
Type of area*								
Urban	NA	NA	60	94%	80	85%	94	95%
Rural	NA	NA	4	6%	14	15%	5	5%
Previous COVID-19 diagnosis since April 1, 2020†	15	10%	8	13%	6	6%	10	10%

Percentages might not add up to 100% due to rounding. DP=data partner. NA=not available. *Urban versus rural status was defined on the basis of five-digit zip codes for enrolled members' physical addresses. This information was not available in the DP1 database. †A previous COVID-19 diagnosis was identified via the International Classification of Diseases (tenth revision, clinical modification) code U07.1.

Table 1: Descriptive characteristics of myocarditis and pericarditis events after mRNA-1273 and BNT162b2 vaccination among people aged 18-64 years in four health plan claims databases

Results: Effects by Gender (cont.)

Table 2. Myocarditis Within 28 Days After a Dose of SARS-CoV-2 Vaccine^a

Subgroup, exposure ^b	No. of events ^c	Follow-up, 1000 person-years	Crude incidence rate per 1000 person-years of follow-up ^d	IRR (95% CI)	No. of excess events in 28 d per 100 000 vaccinees (95% CI)
Males, ages ≥12 y					
Unvaccinated	520	5340.6	0.097	1 [Reference]	0 [Reference]
AZD1222	6	43.0	0.139	2.39 (1.04 to 5.48)	0.62 (0.00 to 1.24)
AZD1222/AZD1222	≤5	29.2	ND	1.29 (0.31 to 5.33)	0.12 (-0.48 to 0.72)
BNT162b2	70	560.9	0.125	1.40 (1.09 to 1.80)	0.27 (0.09 to 0.46)
BNT162b2/BNT162b2	85	495.0	0.172	2.04 (1.61 to 2.58)	0.67 (0.46 to 0.88)
BNT162b2/mRNA-1273	34	23.7	1.433	16.99 (11.51 to 25.07)	10.34 (6.86 to 13.83)
mRNA-1273	13	93.2	0.139	1.45 (0.84 to 2.52)	0.33 (-0.11 to 0.78)
mRNA-1273/mRNA-1273	53	72.3	0.733	8.55 (6.40 to 11.41)	4.97 (3.62 to 6.32)
Males, ages 16-24 y					
Unvaccinated	149	794.6	0.188	1 [Reference]	0 [Reference]
AZD1222	0	0.70	ND	ND	ND
AZD1222/AZD1222	0	0.10	ND	ND	ND
BNT162b2	24	63.9	0.376	2.16 (1.40 to 3.33)	1.55 (0.70 to 2.39)
BNT162b2/BNT162b2	37	41.5	0.891	5.31 (3.68 to 7.68)	5.55 (3.70 to 7.39)
BNT162b2/mRNA-1273	17	4.6	3.687	35.62 (18.87 to 67.25)	27.49 (14.41 to 40.56)
mRNA-1273	≤5	11.5	ND	2.90 (1.05 to 7.97)	1.75 (-0.20 to 3.71)
mRNA-1273/mRNA-1273	15	5.8	2.584	13.83 (8.08 to 23.68)	18.39 (9.05 to 27.72)

Females, ages ≥12 y					
Unvaccinated	211	4942.2	0.043	1 [Reference]	0 [Reference]
AZD1222	≤5	64.1	ND	1.87 (0.58 to 6.03)	0.17 (-0.13 to 0.46)
AZD1222/AZD1222	≤5	31.6	ND	1.67 (0.40 to 6.97)	0.19 (-0.30 to 0.69)
BNT162b2	35	572.3	0.061	1.46 (1.01 to 2.11)	0.15 (0.02 to 0.28)
BNT162b2/BNT162b2	30	522.7	0.057	1.25 (0.77 to 2.05)	0.09 (-0.09 to 0.26)
BNT162b2/mRNA-1273	≤5	19.1	ND	9.62 (3.11 to 29.77)	1.44 (0.02 to 2.87)
mRNA-1273	≤5	90	ND	1.45 (0.35 to 5.97)	0.05 (-0.13 to 0.23)
mRNA-1273/mRNA-1273	7	71.6	0.098	2.73 (1.27 to 5.87)	0.48 (0.07 to 0.89)

Females, ages ≥40 y					
Unvaccinated	137	2541.6	0.054	1 [Reference]	0 [Reference]
AZD1222	≤5	52.9	ND	ND	ND
AZD1222/AZD1222	≤5	30	ND	ND	ND
BNT162b2	27	392.5	0.069	1.37 (0.90 to 2.08)	0.14 (-0.03 to 0.31)
BNT162b2/BNT162b2	20	388.1	0.052	1.02 (0.63 to 1.65)	0.01 (-0.18 to 0.20)
BNT162b2/mRNA-1273	≤5	7.5	ND	8.12 (1.83 to 36.00)	1.79 (-0.72 to 4.29)
mRNA-1273	≤5	48.5	ND	4.68 (0.60 to 36.45)	0.12 (-0.13 to 0.38)
mRNA-1273/mRNA-1273	≤5	44.4	ND	3.03 (1.10 to 8.31)	0.46 (-0.05 to 0.97)

Discussion

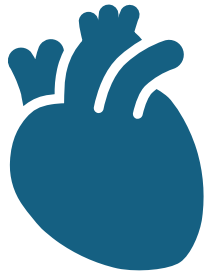
Vaccine hesitancy

- Fueled by mistrust of public health officials, conspiracy theories, misinformation, and concerns about the rapid development of the vaccine.
- Influenced by a variety of demographic factors (Ahmed et al., 2023)

Safety and efficacy of the vaccine

- BNT162b2 (Pfizer) was shown to be 95% effective in preventing SARS-CoV-2 infections (Polack et al., 2020)
 - 0.5% systemic adverse events following vaccination observed across demographic groups such as age, race, ethnicity, sex, and BMI
- 91.3% effective against SARS-CoV-2 infections and 96.7% effective against serious disease (Thomas et al., 2021)

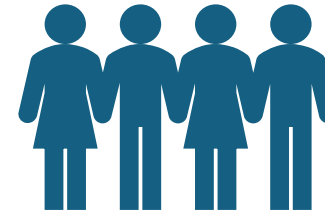
Discussion (cont.)



Approaches to treating cardiovascular effects

Primarily treated using pharmaceuticals

- Myocarditis/pericarditis
- Tachycardia and arrhythmia
- Thromboembolism
- Thrombocytopenia



Opportunities for future research

- Race
- Ethnicity
- Socioeconomic status

References

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